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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,843	10/31/2003	Eric Hammill	279.581USI	9309
21186 7590 10/05/2007 SCHWEGMAN, LUNDBERG & WOESSNER, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402			EXAMINER SMITH, TERRI L	
			ART UNIT 3762	PAPER NUMBER
			MAIL DATE 10/05/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/698,843		HAMMILL ET AL.	
	Examiner		Art Unit	
	Terri L. Smith		3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 and 26-38 is/are pending in the application.
- 4a) Of the above claim(s) 14-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-13, 24 and 26-38 is/are rejected.
- 7) ☒ Claim(s) 6, 7 and 30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8-24-07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 24 August 2007 has been entered.

Response to Arguments

2. Applicant's arguments filed on 24 August 2007 have been fully considered but they are not persuasive. As stated in the Office Action mailed on 24 May 2007 and re-stated herein below Examiner respectfully disagrees with the Applicant's arguments stated in the **REMARKS** on page 8, last line–page 9, line 14 (which are repeats from the Applicant's **REMARKS** mailed on 26 September 2006 on page 10, lines 3–6 and 11–16). Again, per Applicant's claims 12 and 13 as set forth in the present invention, the means for detecting wear of the insulating layer is stated to be a conductive sleeve disposed within the insulating layer.

In the Office Action mailed on 26 May 2006 on page 4 lines 3–5 and page 5 lines 1–3, Examiner cited where the equivalence structure corresponding to the elements disclosed in the specification is found in the Verness prior art, as required by the MPEP § 2183. Specifically, Verness discloses a conductive sleeve in FIG. 15 element 422 within an insulative layer (e.g., element 410). It is noted that the specification is not consistent with the claim in that it does not explicitly disclose how the conductive sleeve detects wear of the insulating layer.

In view of the many pages cited by the Applicant in the written description that allegedly disclose the means plus function language in claim 11, **Examiner is requesting under 37 CFR**

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1.75 that Applicant specifically state on the record what SPECIFIC elements comprise the means for detecting wear. A reply pointing to general written description pages or general elements or not address this will be held DELIBERATE NON-RESPONSIVE. After

reading the many pages in the written description cited by the Applicant, the Examiner found that the cited areas commonly stated “at least one conductive sleeve disposed within the insulating layer” as it pertains to detecting wear of the insulating layer, which is consistent with the claim language set forth in claims 12–13 in the present invention. Consequently, Examiner maintains claims 11–13 rejected under 35 U.S.C. 102(b) as being anticipated by Verness et al., U.S. Patent 6,285,910.

3. Regarding Applicant’s traversal of the rejections of claims 1–13 and 24–33, with the exception of the amended language, Examiner respectfully disagrees. Applicant’s arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

With respect to Applicant’s traversal of the rejections of claims 1–13 and 24–33 relating to the amended language, Examiner respectfully disagrees. According to *The American Heritage Dictionary Second College Edition* Copyright © 1982, the definition for axially is: located on, around, or in the direction of an axis. In the broadest reasonable interpretation, the conductive sleeve (e.g., element 24) identified in the prior art of Yang et al., U.S. Patent 5,824,030, is extends axially along the conductor by virtue of it being located on, around, or in the direction of an axis as defined herein above.

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Additionally, the conductive sleeve is electrically isolated from the conductor (e.g., element 52) identified in the prior art of Yang et al. as described in Figs. 7–8 and column 7, lines 1–5 where atrial electrode element 24 (being interpreted as the conductive sleeve in the presently claimed invention) is connected to conductor 50 which is electrically isolated from conductor 52 (being interpreted as the conductor in the presently claimed invention).

Consequently, Examiner maintains claims 1–10, 24 and 26–33 rejected under 35 U.S.C. 102(b) as being anticipated by Yang et al., U.S. Patent 5,824,030 including the appropriate rejections for the amendments.

Drawings

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 120, insulating layer in Fig. 12 as described on page 13 in the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office Action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the Examiner, the Applicant will be notified and informed of any required corrective action in the next Office Action. The objection to the drawings will not be held in abeyance.

Claim Objections

5. Claims 11–13 are objected to under 37 CFR § 1.75(d)(1) which provides, in part, that “the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.” In claims 11–13, regarding the “means for language,” Applicant must clearly state on the record what structure, materials, or acts perform the function recited in the means- (or step-) plus-function limitation. See 37 CFR § 1.75(d) and MPEP § 608.01(o)

6. Claim 27 is objected to because of the following informalities: To properly claim the surrounding environment, insert the word “wherein” in front of the word “when” in line 1.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the Applicant regards as his invention.

8. Claims 11–13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims, the “means for detecting wear” is vague since it is unclear what elements comprise the means for detecting wear.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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10. Claims 11–13 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Verness et al., U.S. Patent 6,285,910.

11. Regarding claims 11–13, Verness et al. disclose an implantable lead (e.g., FIG. 1) a lead body and an insulating layer (e.g., element 10-lead body; column 2, lines 49–51); a conductor (e.g.,) and an electrode (e.g., FIGS. 6–7, elements 116, 118 and 16; column 5, lines 33–49 and column 6, lines 7–19); and

means for detecting wear of an insulating layer includes a conductive sleeve (e.g., FIG. 15, element 422; column 7, lines 57–61 where the conductive sleeve within the insulative layer is the means for detecting wear of an insulating layer as set forth in claim 12 in the present invention) and is adapted for exposure with a surrounding environment (claim 13) (e.g., column 7, line 57–column 8 line 4 where it is the Examiner's position that the surrounding environment is the lumen in which the conductive sleeve resides).

Further, the conductive sleeve in Verness et al. is an equivalent element because it is interchangeable with the corresponding conductive sleeve disclosed in the specification because it is disposed within an insulating layer and it is exposed with a surrounding environment (both as described herein above). See MPEP 2184 II. (B)

12. With respect to claim 36, Verness et al. disclose a connector (e.g., element 24) and an impedance monitoring device (e.g., column 4, lines 16–47).

13. Claims 1, 2, 4–10, 24 and 26–33 are rejected under 35 U.S.C. 102(b) as being anticipated by Yang et al., U.S. Patent 5,824,030.

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14. Regarding claims 1, 2, 4, 24, 26–28, 32, and 33 Yang et al. disclose an implantable lead assembly (e.g., Figs. 1–8) comprising: a lead body (e.g., element 16), an insulating layer (e.g., elements 25-sheath and 33-expandable member), a conductor (e.g., element 52), an electrode (e.g., element 17),

and at least one conductive sleeve e.g., as shown at in Fig. 8, element 24-electrode, which Examiner is interpreting as a conductive sleeve, surrounds and partially surrounds conductor 52

and extends axially along a conductor e.g., as shown in Fig. 5, column 6, lines 51–55, and as defined by axially herein above

and it is electrically isolated from an electrode, 17 and a conductor, 52 e.g., as shown in Figs. 7–8 and column 7, lines 1–5 where atrial electrode element 24 (being interpreted as the conductive sleeve in the presently claimed invention) is connected to conductor 50 which is electrically isolated from conductor 52 (being interpreted as the conductor in the presently claimed invention)

and from a surrounding environment (e.g. as shown at element 24-electrode in Fig. 8, where it is the Examiner's position that the conductive sleeve is electrically isolated from the lead body 16 and insulating layer 25 which are a surrounding environment).

While Yang et al. do not state a conductive sleeve has first and second impedance values in first and second conditions, respectively, and Applicant has not stated what constitutes a first or second impedance value and condition, it is known that all materials have a resistance (impedance) to electricity in any given condition and therefore it inherently has a first impedance before it is implanted (first condition) and a second impedance after implantation (second condition).

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15. With respect to claims 5, 6, 8 and 29–31, Yang et al. disclose a second conductive sleeve surrounds a conductor and at least one conductive sleeve (e.g., Fig. 8, elements 37-window, which Examiner is interpreting as a second conductive sleeve surrounding conductor 52 and conductive sleeve 24 and it is electrically isolated from electrode 17; column 6, line 45) and a second conductor (e.g., element 50).

16. Regarding claim 7, Yang et al. disclose a first portion (e.g., element 16-lead body), a second portion (e.g., 25-sheath) and a third portion (33-expandable member) (e.g., all elements as shown in Figs. 2 and 8).

17. With respect to claims 9–10, Yang et al. disclose a pulse generator (e.g., column 14, line 5); a monitoring unit (e.g., column 8, lines 46–49 where it is the Examiner's position that the circuitry in the ICD serves as a monitoring unit in that, to monitor is defined as: to keep track of by or as if by an electronic device).

18. Claims 1–5, 8–13, 24, 26–29 and 31–37 are rejected under 35 U.S.C. 102(b) as being anticipated by Verness, U.S. Patent Publication 2002/0099430.

19. Regarding claims 1, 2, 11–13, 24, 26, 27, 32 and 33 Verness discloses an implantable lead assembly (e.g., FIGS. 1–32) comprising: a lead body (e.g., element 10), an insulating layer (e.g., element 230; paragraph [0042], lines 1–3); a conductor (e.g., element 118); an electrode (e.g., element 16);

at least one conductive sleeve (e.g., elements 12 and 574-defibrillation coil electrodes) disposed within insulating layer disposed within an insulating layer and interposed between a

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lead body exterior and a conductor (e.g., as shown in FIGS. 6–7 at element 230) extends axially along a conductor, 118 and is electrically isolated from electrode, 16 and conductor 118;

While Verness does not state a conductive sleeve has first and second impedance values in first and second conditions, respectively, and Applicant has not stated what constitutes first or second conditions and impedance values, it is known that all materials have a resistance (impedance) to electricity in any given condition and therefore it inherently has a first impedance before it is implanted (first condition) and a second impedance after implantation (second condition). Additionally, in paragraph [0047], it is noted that Verness does disclose how the device does indeed identify and handle lead impedance situations.

and means for detecting wear of an insulating layer includes a conductive sleeve (e.g., (e.g., elements 12 and 574-defibrillation coil electrodes where the conductive sleeve within the insulative layer is the means for detecting wear of an insulating layer as set forth in claim 12 in the present invention) and is adapted for exposure with a surrounding environment (claim 13) (e.g., as shown in FIGS. 6–7 at element 230 where, when implanted, the surrounding environment will be the internal area of the body).

Further, the conductive sleeve in Verness is an equivalent element because it is interchangeable with the corresponding conductive sleeve disclosed in the specification because it is disposed within an insulating layer and it is exposed with a surrounding environment (both as described herein above). See MPEP 2184 II. (B)

20. With respect to claims 9–10, Verness discloses a pulse generator (e.g., paragraph [0046], lines 22–23); a monitoring unit (e.g., paragraph [0047], lines 19–20).

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21. Regarding claims 3, 4, 28 and 34, Verness discloses an opening (claim 3) (e.g., element 575); at least one conductive sleeve extends through a lead body (claims 4 and 28) (e.g., 574-defibrillation coil electrode as shown in the embodiment of FIG. 32); a first non-breached condition (e.g., in FIG. 32 where coil 574 is inside of lead body 570) and a second breached condition (e.g., element 575).

22. Regarding claims 5, 8, 29 and 31, Verness discloses a second conductive sleeve (claims 5 and 29) (e.g., element 418A-safety cable) and a second conductor (claims 8 and 31) (e.g., element 416A-conductor cable).

23. With respect to claims 35–37, Verness discloses a connector (e.g., element 30); and an impedance monitoring device (e.g., paragraph [0047], lines 19–20).

Claim Rejections - 35 USC § 103

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

25. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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26. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al., U.S. Patent 5,824,030 or Verness, U.S. Patent Publication 2002/0099430.

Yang et al. and Verness disclose the essential features of the claimed invention as described above but does not disclose expressly a plurality of discrete conductive elements. It would have been an obvious matter of engineering design choice to one of ordinary skill in the art at the time the invention was made to modify the conductive sleeve as taught by Yang et al. or Verness, to have a plurality of discrete conductive elements, because Applicant has not disclosed that a plurality of discrete conductive elements provides an advantage, is used for a particular purpose, or solves a stated problem.

One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the conductive sleeve as taught by Yang et al. or Verness, because the conductive sleeve performs functional status monitoring similarly to that of the Applicant's claimed invention.

Therefore, it would have been an obvious matter of engineering design choice to modify the conductive sleeve to obtain the invention as specified in the claim.

Conclusion

27. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is (571) 272-7146. The Examiner can normally be reached on Monday - Friday between 7:30 a.m. - 4:30 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

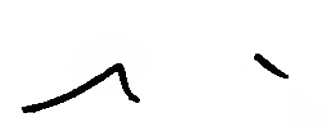
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



TLS

September 28, 2007

28 September 2007
GEORGE R. EVANISKO
PRIMARY EXAMINER*9/29/7*